

K124029



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510(k) Summary

MAR 27 2013

Submitted By: Microline Surgical

Contact Person: Bill McCallum

Date Prepared: February 19, 2013

Proprietary Name: Microline Flexible Ligating Shears

Classification Name: Electrosurgical Cutting and Coagulation and Accessories
21 CFR § 878.4400
79 GEI

Predicate Devices: This product is similar in design, composition, to and function to the:
Thermal Ligating Shears (K062257) cleared on October 10, 2006 and the
Spider Flexible Monopolar Surgical Instruments (K122299) cleared on
October 25, 2012.

Device Description and Technological Characteristics:

The Microline Flexible Ligating Shears system consists of the following:

Microline Flexible Ligating Shears
Microline Universal Power Supply
Single or multiple access port device such as the TransEnterix SPIDER Single Port.

The Microline Flexible Ligating Shears are designed to provide thermal ligation and division during minimally invasive abdominal laparoscopic surgery. The Microline Flexible Ligating Shears consist of a sterile single patient use handpiece. The device has heating elements at the distal tip which are activated by a finger switch located on the handpiece of the device. The Microline Universal Power Supply is designed to allow the surgeon control of the heating element power of the device in order to accommodate for individual patient anatomy. An instrument cord is attached to the handpiece and is plugged into the dedicated Microline Universal Power Supply.

The Microline Flexible Ligating Shears are designed to be used with an Introducer such as the SPIDER Single Port Device.

Confidence, simply delivered.



The Microline Flexible Ligating Shears are supplied sterile in a Tyvek/Mylar sterilization pouch on a mounting card and thermoformed tray, placed in a fiberboard carton. The device is intended to be used by a trained physician for a single patient use during minimally invasive abdominal laparoscopic surgery.

The Microline Flexible Ligating Shears power cable is attached to the handle of the instrument handpiece and connects to the Microline Universal Power Supply. The Universal Power Supply is supplied non-sterile for reusable use outside the sterile field.

The Microline Flexible Ligating Shears incorporates Hi and Low heating modes that are used to cauterize and cut soft tissue. The heating elements in the tip are activated by a physician controlled finger switch located on the handpiece of the device. The Microline Flexible Ligating Shears is intended to provide general purpose cauterization, dissection, spreading, and grasping of soft tissue during minimally invasive or open surgical procedures.

Principle of Operation:

The Microline Flexible Ligating Shears provide a path of entry to the surgical target by the SPIDER device's flexible extended IDTs (Instrument Delivery Tube), also called the SPIDER Single Port Device. Two (2) flexible channels known as IDTs (Instrument Delivery Tubes) are positioned horizontally to the operative plane and include extended flexible lumens to facilitate manipulation of surgical instruments, enabling control over operator determined distances. The IDTs facilitate x, y, and z motion to allow for a multidirectional and triangulated approach within the surgical field. This mimics the approach of standard laparoscopic surgery using multiple incisions.

The flexible IDTs provide 360 degrees of freedom at the distal tips. The right hand controls the right instrument and the left hand controls the left instrument. Two (2) rigid channels positioned vertically to the operative field enable the use of an endoscope and any other surgical instruments.

Indications for Use:

The Microline Flexible Ligating Shears are intended for simultaneous cutting and cauterization of soft tissue during minimally invasive abdominal laparoscopic surgery. The device may also be used for cutting natural, non-metallic sutures during surgery.

Performance Testing:

The Microline Flexible Ligating Shears have been tested for functionality and they have found to perform their intended functions for minimally invasive abdominal laparoscopic procedures. Additionally, testing has proven that they perform their ligating functions. The device has also been tested with the SPIDER® device and passed all required testing for system compatibility.

The Microline Thermal Ligating Shears have been sterilized to a SAL of 1×10^{-6} using gamma irradiation. The gamma sterilization process was validated to the following: - Clause 9, Method VDmax - Substantiation of 25 kGy or 15 kGy as the sterilization dose in ISO 11137-2. Sterile barrier testing has



been performed and it has been shown that the sterile barrier has the capability of maintaining sterility during the required shelf life, and that the device itself maintains its performance requirements.

Biocompatibility testing was successfully conducted on the Microline Flexible Ligating Shears in accordance with ANSI/AAMI/ISO 10993-1. The Microline Flexible Ligating Shears falls into the category of external communicating device and the appropriate tests were performed as described in Table A.1 in Annex A of ANSI/AAMI/ISO 10993-1.

The Microline Flexible Ligating Shears were evaluated by an independent testing laboratory and found compliant to IEC 60601-1:1988 + A1:1999 + A2:1995 general requirements for basic safety, including all US, CAN National Differences.

As illustrated in the Predicate Comparison Table below, the Microline Flexible Ligating Shears do not incorporate any significant technological differences that effect safety and efficacy. Therefore clinical data was not necessary for evaluation of substantial equivalence. The verification and validation test results are sufficient to demonstrate safety and effectiveness when compared to the predicate devices. The minor design or material differences between The Microline Thermal Ligating Shears and the predicate devices have been evaluated and tested and found to present no new issues of safety and effectiveness.

Predicate Comparison Table:

Characteristic	Starion Instruments Corporation TLS3 Thermal Ligating Shears 510(k) K062257 (Predicate device)	Microline Flexible Ligating Shears (subject of this submission)	Transenterix Spider Flexible Monopolar Surgical Instruments K122299 (Predicate device)
Indications for Use	For the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, non-metallic sutures during surgery.	The Microline Flexible Ligating Shears are intended for simultaneous cutting and cauterization of soft tissue during minimally invasive abdominal laparoscopic surgery. The device may also be used for cutting natural, non-metallic sutures during surgery.	The Spider Surgical Instruments are intended for use on minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, suction/irrigation and other manipulation of tissues and vessels during laparoscopic surgery.
Principle of Operation	Heat is conducted to tissue compressed within the jaws via heating elements in the instrument tip.	Same	Monopolar high frequency current passes from active jaw tips of instrument to cut a coagulate tissue at the immediate surgical site, flowing through the patient to an adhesive electrode return pad connected to the monopolar electrosurgical generator.
Energy Source	Electrical current from Starion Instruments Universal Power Supply (UPS)	Same	Electrical high frequency current and voltage from a third party monopolar electrosurgical unit (ESU).



Method of Actuation	Finger switch	Same	Same
Sterility	Gamma radiation, sterility assurance level (SAL) is 10 ⁻⁶	Same	Same
Cleaning and re-sterilization of the reusable hand piece	N/A Sterile for single use only.	Same	Same
Primary Sterile Barrier	Tyvek/Mylar pouch	Same	Same
Biocompatibility	All patient contact materials meet biocompatibility test per ISO 10993-1	Same	Same
Energy Used and/or Delivered	Maximum Output - 60W	Same	Monopolar high frequency output.
Rigidity/Flexibility	Rigid, not flexible	Functions with the TransEnterix SPIDER Single Port Device	Functions with the TransEnterix SPIDER Single Port Device

Summary:

The information provided demonstrates that the Microline Flexible Ligating Shears is substantially equivalent to the Thermal Ligating Shears (K062257) and the Spider Flexible Monopolar Surgical Instruments (K122299) cleared on October 25, 2012, in function, intended use and indications for use.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Microline, Surgical, Incorporated
% Mr. Bill McCallum
Regulatory Affairs Manager
800 Cummings Center, Suite 166T
Beverly, Massachusetts 01915

March 27, 2013

Re: K124029

Trade/Device Name: Microline Flexible Ligating Shears
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device
and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 26, 2012
Received: December 28, 2012

Dear Mr. McCallum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K124029

Indications for Use

Device Name: Microline Flexible Ligating Shears

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The Microline Flexible Ligating Shears are intended for simultaneous cutting and cauterization of soft tissue during minimally invasive abdominal laparoscopic surgery. The device may also be used for cutting natural, non-metallic sutures during surgery.

Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C.
Nipper -S

For

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K124029